IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER; TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404; and UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFIT FUND, on behalf of themselves and all others similarly situated,	)	No. 13-cv-5865
	)	Judge Sara L. Ellis
Plaintiffs,	)	
v.	)	
ABBOTT LABORATORIES and ABBVIE INC.,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS ABBOTT LABORATORIES AND ABBVIE INC.'S MOTION TO DISMISS

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Defendants Abbott Laboratories and AbbVie Inc. (together, "Abbott") respectfully submit this memorandum of law in support of their motion to dismiss the Class Action Complaint of Plaintiffs Sidney Hillman Health Center of Rochester, Teamsters Health Services and Insurance Plan Local 404, and United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund.

INTRODUCTION

This is a civil RICO class action, brought by three health-benefit providers (essentially, insurers) who pay for their beneficiaries' prescriptions, on behalf of every such third-party payor ("TPP") in the United States. Plaintiffs allege that Abbott promoted its prescription drug Depakote "off-label"—that is, for treatment of conditions beyond those for which it has been approved by the United States Food and Drug Administration ("FDA"). Plaintiffs allege that Abbott's promotion wrongfully caused them to pay for off-label Depakote prescriptions.

In the last few years, TPPs have filed a wave of RICO suits against pharmaceutical companies based on off-label promotion. Like this lawsuit, they have generally been attempts to piggyback on proceedings brought by, or in the name of, the federal government. And save for a lone outlier, these cases have all been dismissed—including a virtually identical off-label RICO case in the Southern District of Illinois, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 80758 (S.D. Ill. Aug. 5, 2010).[1]

[1] *See also Emp'r Teamsters-Local Nos. 17/505 Health Welfare Trust Fund v. Bristol Myers Squibb Co.*, 2013 U.S. Dist. LEXIS 21589 (S.D. W. Va. Jan. 29, 2013); *In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 111446 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp. v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 89759 (E.D. Tex. Apr. 23, 2012), *report and recommendation adopted*, 2012 U.S. Dist. LEXIS 89758 (E.D. Tex. June 28, 2012); *Health Care Serv. Corp. v. Olivares*, 2011 U.S. Dist. LEXIS 117750 (E.D. Tex. Sept. 2, 2011), *report and recommendation adopted*, 2011 U.S. Dist. LEXIS 112544 (E.D. Tex. Sept. 30, 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900 (D.N.J. July 10, 2009), *aff'd*, 678 F.3d 235 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270 (S.D. Fla. 2009), *aff'd*, 444 F. App'x 401

As in those cases, Plaintiffs' RICO claims suffer from profound defects. First, Plaintiffs fail to allege a cognizable injury. Second, Plaintiffs adequately plead neither "but-for" nor proximate causation. Third, Plaintiffs fail to allege that Abbott acted on behalf of an independent criminal "enterprise," rather than in its own corporate self-interest. Fourth, Plaintiffs fail to plead two predicate acts of "racketeering." And fifth, Plaintiffs' claims are time-barred. Plaintiffs' state-law claims also fail, for largely the same reasons.

This action, therefore, should be dismissed in its entirety, with prejudice.

BACKGROUND

"Off-Label" Promotion And Prescribing

Under the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, new drugs require FDA approval prior to sale. *Id.* § 355(a). To secure approval, the manufacturer must demonstrate that the drug is safe and effective for the medical conditions (or "indications") described on the proposed label. *Id.* § 355(d)(4)-(5). This showing usually requires two double-blind, randomized, controlled clinical trials for each such indication. 21 C.F.R. § 314.126.

Post-approval, "[t]he FDCA…do[es] not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use." *United States v. Caronia*, 703 F.3d 149, 154-55 (2d Cir. 2012). However, FDA asserts that such a prohibition is implicit in the statute, and until recently, most courts agreed. *Id.* The constitutionality of FDA's interpretation is now in doubt. *See*

(11th Cir. 2011); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011); *Cent. Reg'l Emp. Benefit Fund v. Cephalon, Inc.*, 2010 U.S. Dist. LEXIS 29677 (D.N.J. Mar. 29, 2010); *S. Ill. Laborers' & Employers Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414 (S.D.N.Y. Sept. 30, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen*, 2008 U.S. Dist. LEXIS 103526 (D.N.J. Dec. 23, 2008), *subsequent order at*, 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282 (C.D. Cal. 2008), *subsequent order at*, 2009 U.S. Dist. LEXIS 58697 (C.D. Cal. June 17, 2009), *aff'd sub. nom., United Food & Comm. Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008), *aff'd*, 634 F.3d 1352 (11th Cir. 2011).

Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing…is…protected by…the First Amendment."); *Caronia*, 703 F.3d at 168-69 (holding that "the government cannot prosecute pharmaceutical manufacturers" for making true statements "promoting…off-label use"). However, regardless of what the FDCA prohibits, the statute "leaves no doubt" that only "the Federal Government" is "authorized to file suit for noncompliance," and that enforcement suits by "private litigants" are barred. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (citing 21 U.S.C. § 337(a)).

Moreover, even assuming off-label *promotion* is unlawful, doctors are expressly permitted to *prescribe* drugs for off-label uses. 21 U.S.C. § 396; *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). And they routinely do: as many as 60% of all prescriptions written in the United States are for off-label uses.[2] *See United States v. King-Vassel*, 728 F.3d 707, 2013 U.S. App. LEXIS 17989, at *3-4 (7th Cir. 2013) (off-label use "ubiquit[ous]").

This makes good sense, because "standards of practice for drug therapies are continually evolving," Am. Med. Ass'n, *Medicare Patient Access*, 18 REPORTS OF BOARD OF TRUSTEES 122, 124 (2004), http://www.ama-assn.org/meetings/public/interim04/bot_reports.pdf, yet the machinery of federal regulation moves slowly. Moreover, medical consensus may shift based on data points less definitive than the "gold standard" (two double-blind, randomized, controlled clinical trials) required for approval of a new label indication. Thus, "FDA-approved uses often lag behind knowledge about actual effective treatment." *Layzer v. Leavitt*, 770 F. Supp. 2d 579, 586 (E.D.N.Y. 2011); *see also King-Vassel*, 2013 U.S. App. LEXIS 17989, at *3.

[2] *See, e.g.*, Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 Hastings L.J. 967, 968 (2007) ("[T]he American Medical Association…[has] estimated that 40% to 60% of prescriptions are for unapproved uses"); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 80 (1998) (off-label use 25-60% generally; more in many specialties).

In light of the foregoing, lack of FDA approval of a drug for a particular use "does not necessarily bear" on whether that use is "medically appropriate." *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989); *see also Richardson v. Miller*, 44 S.W.3d 1, 12 (Tenn. Ct. App. 2000) ("[L]ack of FDA approval…for a particular use does not imply that…[it] is either disapproved or improper."); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 84 (1998) ("[I]t is not possible to draw any conclusion about…safety or effectiveness…from the administrative/legal status of [a] use as off-label."). Indeed, the Supreme Court has "recognize[d] the value and propriety of off-label use," noting that it is "widespread in the medical community and often…essential to giving patients optimal medical care." *Buckman*, 531 U.S. at 350, 351 n.5.

Overview Of Depakote

Depakote (divalproex sodium) was approved for sale by FDA in 1983. *See* Drugs@FDA, Drug Details (Cavanaugh Decl., Ex. A).[3] FDA has approved Depakote for three indications:

- mania, *i.e.*, "treatment of the manic episodes associated with bipolar disorder";
- epilepsy, *i.e.*, "monotherapy and adjunctive therapy in the treatment of patients with [various types of epileptic] seizures";
- migraine, *i.e.*, "prophylaxis of migraine headaches."

Drugs@FDA, Depakote Label (Cavanaugh Decl., Ex. B) ¶¶ 1.1-1.3.

Depakote also has a number of medically recognized off-label uses. Those uses, as noted by authoritative drug-information compendia,[4] include the following:

[3] This court "may…judicially notice public records and government documents…available from reliable sources on the Internet." *Bova v. U.S. Bank, N.A.*, 446 F. Supp. 2d 926, 931 n.2 (S.D. Ill. 2006).

[4] Under the Medicaid Act, a use of a drug is deemed "medically accepted" if *either* FDA has approved the drug for that use, *or* the use is mentioned in any of three specified drug-information compendia, including the two cited herein: DrugDex® Information System ("DrugDex") (Cavanaugh Decl., Ex. C) and American Hospital Formulary Service Drug Information ("AHFS-DI") (Cavanaugh Decl., Ex. D). 42 U.S.C. § 1396r-8(k)(6); *see King-Vassel*, 2013 U.S. App. LEXIS 17989, at *21-23; *Layzer*, 770 F. Supp.

- **Agitation Associated with Dementia:** In clinical studies, Depakote "improve[d] symptoms of agitation" in dementia patients. DrugDex at 193-94; 201-02.

- **Attention Deficit/Hyperactivity Disorder (ADHD):** "Some experts recommend" Depakote for "treatment of aggressive outbursts in children with ADHD." AHFS-DI at 2297.

- **Bipolar Depression:** "[S]ome evidence suggests" Depakote "may be moderately effective in the prophylaxis of [bipolar] depressive episodes." AHFS-DI at 2296.

- **Developmental Disorders:** Patients with developmental disorders (including autism, Asperger's, and "pervasive developmental disorder") have shown "some improvement with [Depakote] treatment." DrugDex at 205-06. Depakote also "appears useful in the management of affective disorders in mentally deficient children and adults." *Id*. at 180.

- **Drug and Alcohol Withdrawal:** "Evidence favors efficacy" of Depakote for use in "treatment of alcohol withdrawal," DrugDex at 192-93, and "[f]our controlled studies and several case reports suggest" that Depakote "may be effective for ethanol and benzodiazepine withdrawal," *id*. at 188-89, 207-08.

- **Schizophrenia and Psychosis:** Depakote may be used "as an adjunct to antipsychotic agents in the symptomatic management of schizophrenia," and "the American Psychiatric Association…state[s] that [it] may be...useful…in [certain categories of] schizophrenic patients." AHFS-DI at 2297; *see also* DrugDex at 206-07 ("[e]vidence favors efficacy" for schizoaffective disorder).

Abbott's Alleged Off-Label Promotion Of Depakote

Beginning in 1998, Abbott allegedly promoted Depakote for various off-label uses. The Complaint focuses on five particular off-label conditions (or groups of conditions): (1) bipolar depression (Compl. ¶¶ 143-61); (2) ADHD and developmental delay in children (*id*. ¶¶ 162-67); (3) drug and alcohol withdrawal (*id*. ¶¶ 168-72); (4) schizophrenia and associated psychosis (*id*. ¶¶ 173-77); and (5) agitation associated with dementia (*id*. ¶¶ 178-86).

Plaintiffs allege, in conclusory fashion, that Depakote "has not been shown to be

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2d at 581. The Court may consider these compendia because they are incorporated by reference in the Medicaid Act and thus have the force of law. *See Alvarez v. Chevron Corp.*, 656 F.3d 925, 929 (9th Cir. 2011); *Getty Petroleum Mktg., Inc. v. Capital Terminal Co.*, 391 F.3d 312, 325-29 (1st Cir. 2004) (Lipez, J., concurring). The Court may also take notice of them because they are standard references in the medical field. *See United States v. N. Ill. Special Recreation Ass'n*, 2013 U.S. Dist. LEXIS 52100, at *9 n.1 (N.D. Ill. Apr. 11, 2013) (taking judicial notice of Physician's Desk Reference on motion to dismiss).

effective," or that "[t]here is no credible evidence that Depakote is effective," in treating these five conditions. (*Id.* ¶¶ 143, 162, 168, 173, 178.) However, as noted above, authoritative drug compendia acknowledge that there *is* evidence of Depakote's effectiveness for each of these conditions. Plaintiffs also assert, in conclusory fashion, that "there were alternative medications that were cheaper, more effective, or had fewer side effects than Depakote." (*Id.* ¶ 205.)

Plaintiffs allege that Abbott promoted Depakote via three different RICO "enterprises":

(1) **The PharmaCare Enterprise:** Abbott allegedly employed an organization called PharmaCare Strategies, Inc. to provide "training sessions for its sales representatives" that "focused on maximizing Depakote sales through off-label promotion." (*Id.* ¶¶ 72-73.) Plaintiffs collectively refer to Abbott, Abbott's sales representatives, and PharmaCare as the "PharmaCare Enterprise." (*Id.* ¶¶ 23-25.)

(2) **The CENE Enterprise:** Abbott allegedly targeted the medical community with programs and printed materials addressing off-label use of Depakote. (*Id.* ¶¶ 17-22, 26-28.) Some of these were provided through the Council for Excellence in Neuroscience Education ("CENE"), a group of doctors that Plaintiffs claim was a front for Abbott's marketing efforts. (*Id.* ¶¶ 17-22.) Plaintiffs refer to the combination of Abbott, CENE, the physicians comprising CENE, and a company called ACCESS (which created CENE's website and certain CENE-distributed materials) as the "CENE Enterprise." (*Id.* ¶ 22.)

(3) **The ABcomm Enterprise:** Abbott allegedly provided other programs and materials addressing off-label use of Depakote through ABcomm, a company that "holds itself out as a provider of training activities for health professionals." (*Id.* ¶¶ 26-29). Plaintiffs refer to Abbott, ABcomm, and the physicians who participated in these programs as the "ABcomm Enterprise." (*Id.* ¶¶ 26-28.)

Plaintiffs allege that these programs and materials were part of a plot to "pay physicians to spread Abbott's off-label marketing message to other physicians." (*Id.* ¶ 85.) Plaintiffs also allege that Abbott failed to disclose its role in funding some of these programs and materials. (*Id.* ¶¶ 103-05, 127, 133, 137-38, 141). However, Plaintiffs do not identify any particular statement made by any physician at Abbott's behest that was false or medically unsound.

Government Proceedings Concerning Off-Label Promotion Of Depakote

Between October 2007 and January 2010, relators filed four *qui tam* complaints against

Abbott under the False Claims Act, alleging that its off-label marketing of Depakote had resulted in inappropriate charges to the federal government. (Compl. ¶¶ 193-95.) The lead *qui tam* case, *United States ex rel. McCoyd v. Abbott Labs.*, No. 1:07-cv-0081 (W.D. Va.), was filed by Grant & Eisenhofer P.A., which is also counsel for Plaintiffs in this action. Large portions of the Complaint in this case are copied almost *verbatim* from the *McCoyd* complaint. *See generally* Complaint in *McCoyd* (Cavanaugh Decl., Ex. E).

In November 2009, Abbott disclosed in a public filing with the Securities and Exchange Commission that federal prosecutors had initiated their own investigation:

> The United States Department of Justice…is investigating Abbott's sales and marketing activities for Depakote[,]…seeking to determine whether any of these activities violated civil and/or criminal laws…in connection with Medicare and/or Medicaid reimbursement to third parties.

Abbott Laboratories Form 10-Q, Nov. 6, 2009, http://www.sec.gov/Archives/edgar/data/1800/000110465909063192/a09-28494_110q.htm. Considerable media coverage followed.[5] In a public opinion issued March 10, 2010, a judge noted that this investigation involved Abbott's "off-label marketing of Depakote…for agitation and aggression in the elderly." *In re Subpoenas*, 692 F. Supp. 2d 602, 603 (W.D. Va. 2010). This, too, triggered significant press coverage.[6]

The United States intervened in all four *qui tam* actions on February 1, 2011, at which point the actions were unsealed. (Compl. ¶ 196.) In October 2011, Abbott announced that "it

[5] *See, e.g.*, DOW JONES BUSINESS NEWS, "US Justice Dept. Probing Depakote Marketing," Nov. 6, 2009; CHICAGO DAILY HERALD, "Abbott faces probe of Depakote," Nov. 7, 2009; CHICAGO TRIBUNE, "Abbott faces probe on Depakote sales," Nov. 7, 2009; CHICAGO SUN-TIMES, "Abbott Labs Probed Over Marketing of Epilepsy Drug," Nov. 7, 2009. These articles are attached as Exhibit H to the Cavanaugh Declaration. The Court may take judicial notice of the fact of their publication. *Specht v. Google, Inc.*, 758 F. Supp. 2d 570, 586 (N.D. Ill. 2010).

[6] *See, e.g.*, DOW JONES BUSINESS NEWS, "US Judge Orders Abbott To Turn Over CEO's Emails For Probe," Apr. 12, 2010; ASSOCIATED PRESS, "Abbott ordered to turn over e-mails for govt [sic] probe," Apr. 13, 2010; WALL STREET JOURNAL, "Abbott Told to Turn Over Emails," Apr. 13, 2010. These articles are attached as Exhibit I to the Cavanaugh Declaration.

was recording a $1.5 billion charge to cover a potential settlement" with the United States of charges "that it promoted…Depakote…for unauthorized uses." NEW YORK TIMES, "Abbott Labs Will Split Into 2 Units," Oct. 20, 2011, at B-1. Again, this announcement was widely reported.[7]

On May 7, 2012, Abbott entered into a $1.6 billion settlement of all of the federal government's civil and criminal claims involving promotion of Depakote. (Compl. ¶ 198.) This made headlines nationwide.[8] As part of the settlement, Abbott pleaded guilty to violating the FDCA. *See* Settlement Agreement (Cavanaugh Decl., Ex. F) at 2; Plea Agreement (Cavanaugh Decl., Ex. G) at 1.[9] Otherwise, Abbott "expressly denie[d] the allegations of the United States and Relators as set forth…in the [*qui tam*] [a]ctions and denie[d] that it engaged in any wrongful conduct." Settlement Agreement at 4.

Plaintiffs' Alleged Injuries

The Complaint is curiously terse as to Plaintiffs' own injuries. They assert, in conclusory fashion, that they "paid or reimbursed eligible beneficiaries' prescription drug benefits for off-label use of Depakote and [were] injured by the conduct alleged" in the Complaint. (Compl. ¶¶ 12-14, 204.) No Plaintiff alleges that it actually paid for any Depakote prescriptions for the five

[7] *See, e.g., id.*; DOW JONES NEWS SERVICE, "Abbott Books $1.5B Charge For Potential Depakote Settlement," Oct. 19, 2011; WALL STREET JOURNAL, "Big Abbott Charge Tied to Marketing," Oct. 20, 2011; CHICAGO TRIBUNE, "$1.5 billion charge for possible Depakote deal," Oct. 20, 2011; BLOOMBERG, "Abbott Said to Agree to Pay $1.3 Billion for Depakote Suits," Oct. 21, 2011. These articles are attached as Exhibit J to the Cavanaugh Declaration.

[8] *See, e.g.*, BLOOMBERG, "Abbott to Pay $1.6 Billion to Settle Depakote Drug Allegations," May 8, 2012; WASHINGTON POST, "Abbott to pay $1.6 billion for illegally marketing drug," May 8, 2012; WALL STREET JOURNAL, "Abbott to Pay $1.6 Billion," May 8, 2012; NEW YORK TIMES, "Abbott Settles Marketing Lawsuit," May 8, 2012; LOS ANGELES TIMES, "Abbott Labs to pay $1.6 billion to end Depakote claims," May 8, 2012; CHICAGO SUN-TIMES, "Abbott Labs paying $1.6B for drug claims," May 8, 2012; CHICAGO TRIBUNE, "Abbott settles Depakote case," May 8, 2012; ABC WORLD NEWS WITH DIANE SAWYER, May 7, 2012. These articles are attached as Exhibit K to the Cavanaugh Declaration.

[9] The Court may take notice of these documents because they appear on the public docket of a sister court, *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994), and because the Complaint (at ¶ 198) incorporates them by reference, *United States v. Wood*, 925 F.2d 1580, 1582 (7th Cir. 1991).

off-label conditions specifically discussed in the Complaint. No Plaintiff identifies any beneficiary who was injured by virtue of being prescribed Depakote, or for whom Depakote did not work for the condition for which it was prescribed. And no Plaintiff alleges that any of its beneficiaries' physicians saw or heard any of Abbott's off-label promotional statements—let alone relied on those statements in writing any prescriptions for which Plaintiffs paid.

Based on the foregoing, Plaintiffs allege a civil RICO violation, conspiracy to commit a civil RICO violation, violations of Illinois's and New York's consumer-fraud statutes, and common-law unjust enrichment. Plaintiffs seek to recover some or all of the "hundreds of millions of dollars they paid to…Abbott…as a result of [its] scheme to increase sales of…Depakote" (*id.* ¶ 1), trebled pursuant to RICO. They also seek to represent a class of "[a]ll [TPPs] in the United States…who…reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA." (*Id.* ¶ 211.)

STANDARD OF REVIEW

A complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[C]onclusory statements" and "naked assertion[s]" are properly ignored in this analysis. *Id.* If a complaint's concrete, well-pleaded facts, taken as true, establish only a "possibility" of liability, or are "merely consistent with" liability, dismissal is required. *Id.*

The level of detail required to state a plausible claim varies with the type of case. "[I]n a potentially complex litigation, or one that by reason of the potential cost of a judgment to the defendant creates [an] '*in terrorem*' effect," a heightened degree of substantiation is necessary. *Limestone Dev. Corp. v. Vill. of Lemont*, 520 F.3d 797, 803 (7th Cir. 2008) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). This concern is "applicable to a RICO case." *Id.*

In addition, "allegations of fraud in a civil RICO complaint are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b)." *Slaney v. Int'l Amateur Athletic Fed'n*, 244 F.3d 580, 597 (7th Cir. 2001). "Accordingly, a RICO plaintiff must, at a minimum, describe the predicate acts of fraud with some specificity and state the time, place, and content of the alleged false representations, the method by which [they] were communicated, and the identities of the parties to [them]." *Id.* Moreover, Rule 9(b) prohibits a plaintiff from cribbing allegations of misconduct from other lawsuits, without "bolster[ing] its complaint" with "firsthand facts or data" showing that *it* was injured by the misconduct described therein. *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 443-45 (7th Cir. 2011).

ARGUMENT

I. Plaintiffs Fail To State A Civil RICO Claim

"[T]he civil provisions of RICO are [among] the most misused statutes in the federal corpus of law." *Goldfine v. Sichenzia*, 118 F. Supp. 2d 392, 394 (S.D.N.Y. 2000); *see also Midw. Grinding Co. v. Spitz*, 976 F.2d 1016, 1025 (7th Cir. 1992) (noting the "widespread abuse of civil RICO"). RICO "is a unique cause of action…concerned with eradicating organized, long-term, habitual criminal activity." *Gamboa v. Velez*, 457 F.3d 703, 705 (7th Cir. 2006). However, the "lure of treble damages and attorney's fees have proven irresistible to plaintiffs," who "persist in trying to fit a square peg into a round hole" by recasting ordinary commercial disputes as civil RICO actions. *Guar. Rate, Inc. v. Barr*, 912 F. Supp. 2d 671, 681 (N.D. Ill. 2012) (quoting *Gamboa*, 457 F.3d at 710). This is such a case.

"In keeping with [its] limited purpose," a RICO violation requires "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Gamboa*, 457 F.3d at 705. A "pattern of racketeering activity" consists of "at least two predicate acts" that are "indictable under a specified list of criminal laws" found in 18 U.S.C. § 1961(1)(B). *Midw. Grinding*, 976

F.2d at 1019. In addition, the statute authorizes private civil suits only by "[a] person injured in his business or property by reason of a [RICO] violation." 18 U.S.C. § 1964(c).

Here, Plaintiffs fail to state a civil RICO claim for at least five reasons: (1) they allege no cognizable "injur[y]" to "business or property"; (2) they have not shown "but-for" and proximate causation; (3) they fail to plead that Abbott's racketeering activity was conducted on behalf of "an enterprise"; (4) they fail to sufficiently plead two predicate acts of racketeering; and (5) their claims are untimely under RICO's statute of limitations.

A. Plaintiffs Fail To Plead A Cognizable Injury

As noted above, a civil RICO claim is available only to a plaintiff who has been "injured in his business or property." 18 U.S.C. § 1964(c). This phrase has a "restrictive significance." *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979). In particular, RICO claims must be premised on a "concrete financial loss," not a "speculative and amorphous" economic harm. *Evans v. City of Chicago*, 434 F.3d 916, 932 (7th Cir. 2006), *disapproved on other grounds by Hill v. Tangherlini*, 724 F.3d 965 (7th Cir. 2013); *see also Steele v. Hosp. Corp. of Am.*, 36 F.3d 69, 70-71 (9th Cir. 1994) (actual "out of…pocket" loss required).

1. Merely Paying For An Off-Label Prescription Is Not An Injury

Plaintiffs appear to believe that, to establish injury, it is enough that Abbott "violated…the Food, Drug and Cosmetics Act" by promoting Depakote off-label (Compl. ¶ 5), and that Plaintiffs "pa[id] for Depakote prescriptions to treat [off-label] conditions." (Compl. ¶ 204; *see also id.* ¶¶ 12, 14.)[10] Plaintiffs are wrong as a matter of law.

There is no private right of action to remedy violations of the FDCA. *Buckman*, 531 U.S. at 349 n.4; *UFCW Unions & Emp'rs Midw. Health Benefits Fund v. Walgreen Co.*, 2012 U.S.

[10] That Abbott's FDCA violations are the crux of the Complaint is confirmed by the definition of the class Plaintiffs seek to represent: all TPPs "who…paid…for Depakote for indications not approved by the FDA," irrespective of the particular indication or the medical evidence supporting it. (*Id.* ¶ 211.)

Dist. LEXIS 104315, at *7-8 (N.D. Ill. July 26, 2012), *aff'd*, 719 F.3d 849 (7th Cir. 2013). Indeed, Congress expressly provided that "all…proceedings for the enforcement" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Courts have refused to permit private plaintiffs to thwart this limitation by recasting claims premised on FDCA violations as RICO claims. *See, e.g.*, *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) ("[W]hat the FDCA does not create directly, RICO cannot create indirectly."), *aff'd sub nom. UFCW Cent. Pa. v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010); *Walgreen*, 2012 U.S. Dist. LEXIS 104315, at *7-8 (same).

But even if Congress had not precluded private enforcement of the FDCA, the mere purchase of drugs marketed or prescribed off-label is not a cognizable "injury." As the Supreme Court has made clear, there is nothing inherently injurious about off-label *prescription* and *use* of pharmaceuticals. To the contrary, they are "valu[able]," "prop[er]," and "often…essential to…optimal medical care." *Buckman*, 531 U.S. at 350, 351 n.5. Courts have therefore been "[un]willing to accept that a plaintiff could somehow be injured" within the meaning of RICO "simply because the drug [it purchased] was marketed off-label." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *33-40 (D.N.J. July 10, 2009) (deeming this theory of injury "patently illogical and plainly untenable"), *aff'd*, 678 F.3d 235 (3d Cir. 2012). Any abstract "taint" supposedly resulting from the manufacturer's upstream marketing violations, standing alone, is at best a "speculative and amorphous" harm, not a "concrete financial loss." *Evans*, 434 F.3d at 932.

Rather, to allege a cognizable "injury to…business or property," a plaintiff must allege that he paid for drugs that were *actually* unsafe or ineffective *as to him*—or, in an action brought by a TPP, as to one or more beneficiaries—and, as a result, failed to "receive the benefit of [his]

bargain." *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *38, *56; *see also Ironworkers Local Union 68 & Participating Emp'rs Health & Welfare Funds v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1360-63 (11th Cir. 2011); *Dist. 1199P Health & Welfare Plan v. Janssen L.P.*, 784 F. Supp. 2d 508, 522-23 (D.N.J. 2011); *cf. Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319-20 (5th Cir. 2002) (dismissing state consumer-fraud suit for lack of "economic injury" where drug allegedly injured "other patients," but plaintiff herself was not injured, received effective treatment, and thus obtained "the benefit of her bargain").

2. Plaintiffs Fail To Plead That They Paid For Depakote Prescriptions That Were Actually Ineffective

Plaintiffs make a perfunctory nod toward challenging Depakote's effectiveness for *some* off-label uses. They list five conditions and baldly allege that Depakote "has not been shown to be effective," and/or that "[t]here is no credible evidence that [it] is effective," in treating them. (Compl. ¶¶ 143, 162, 168, 173, 178.) These allegations are insufficient for multiple reasons.

First, the Complaint's few paltry allegations concerning Depakote's effectiveness are "so intertwined with" its copious, non-actionable allegations of off-label promotion that it is impossible to tease them apart. *Epogen*, 590 F. Supp. 2d at 1292. Under these circumstances, it is proper to "dismiss the Complaint in its entirety." *Id.*; *see also In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011).

Second, these statements are "naked assertion[s]," and accordingly, should be disregarded. *Iqbal*, 556 U.S. at 678; *see Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *53 ("[T]he Court simply will not accept Plaintiffs' conclusory allegations…that the Subject Drugs were ineffective."); *Epogen*, 2009 U.S. Dist. LEXIS 58697, at *21-22 (similar). In fact, as noted above, authoritative drug compendia cite evidence that Depakote *is* effective for each of these conditions. Especially in light of that fact, Plaintiffs' conclusory assertions do not "nudge[]"

their claim of injury "across the line from conceivable to plausible." *Iqbal*, 556 U.S. at 680.

Third, merely alleging an *absence of evidence* of effectiveness cannot state a cognizable injury. Unlike the FDA approval process, where a drug is presumed ineffective until the manufacturer proves otherwise, in private litigation, *the plaintiff* must prove that a product *actually lacks* the advertised properties in order to recover. *See Yacub v. Sandoz Pharms. Corp.*, 85 F. Supp. 2d 817, 819 (S.D. Ohio 1999) (noting that the manufacturer "maintain[s] the burden of proof" before the FDA, while "the [p]laintiff bears the burden of proof in [tort] litigation"). Thus, to state a concrete financial loss, "[i]t is simply not enough to claim that [a drug] had not been *proven* to be effective"; rather, "[p]laintiffs must allege" that the drug was actually "ineffective." *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *46-49 (emphasis added).

Fourth and finally, even assuming that Depakote is ineffective for the five conditions addressed in the Complaint, Plaintiffs plead no "firsthand facts or data" showing that *they themselves* were injured, as opposed to unspecified members of the putative class. *Pirelli*, 631 F.3d at 445; *see also Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *53 ("[P]laintiffs…must allege and show that they personally have been injured, not that injury has been suffered by…unidentified members of the class." (quoting *Lewis v. Casey*, 518 U.S. 343, 347 (1996)).

Plaintiffs recapitulate over 40 pages of allegations of wrongdoing drawn from the *McCoyd* complaint, then tack on a conclusory paragraph stating that these actions caused them harm. (Compl. ¶ 204.) But this is not enough. In *Pirelli*, the Seventh Circuit upheld the dismissal of a TPP's complaint, even though it provided a wealth of detail about the fraudulent scheme, because those allegations were cribbed from "a complaint filed in a…*qui tam* action," and the TPP had not provided "firsthand facts or data" showing that *it* was among those the scheme had injured. 631 F.3d at 440, 443-45; *accord In re Schering-Plough Intron/Temodar*

Consumer Class Action, 2010 U.S. Dist. LEXIS 56613, at *29-30 (D.N.J. June 9, 2010) (criticizing plaintiff's "belie[f] that somehow, [merely] through the incorporation of allegations made in [*qui tam*] proceedings,…she can pursue her own relief against Schering"), *aff'd*, 678 F.3d 235 (3d Cir. 2012).

So too here. Plaintiffs fail to "identify…any instances in which…they, themselves, paid" for Depakote for the five off-label indications addressed in the Complaint—as opposed to "other indications for which [its] effectiveness…is unquestioned." *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *91-92. Plaintiffs also fail to plead actual facts showing that even one of their beneficiaries was harmed by, or failed to receive relief from, an off-label Depakote prescription. *See Janssen*, 784 F. Supp. 2d at 521-22 (no injury where plaintiffs "d[id] not identify any [beneficiary] who received an ineffective or unsafe off-label Risperdal prescription").[11] Nor do Plaintiffs have any excuse for this failure, as the necessary information "would not be the product of discovery, but of a more fulsome look at [their] own data." *Pirelli*, 631 F.3d at 444.

3. Plaintiffs Cannot State An Injury Based Solely On The Availability Of Less Expensive Alternatives

As noted above, the Complaint asserts that "there were alternative medications that were cheaper…than Depakote." (Compl. ¶ 205.)[12] But the mere existence of "cheaper" alternatives cannot establish a RICO injury.

Once again, the relevant question is whether Plaintiffs received the benefit of their bargain. If Abbott promoted Depakote as effective for certain conditions, Plaintiffs paid

[11] The generic allegation that unidentified "[p]atients, including those whose prescription drug charges were paid by class members,…received no greater relief from, *or* treatment of, their medical conditions than they would have received from a placebo *and/or* were subject to additional side effects" is patently insufficient under *Iqbal*. (Compl. ¶ 204 (emphasis added).)

[12] Not only is this boilerplate allegation inadequate under *Iqbal*, it is contrary to the Complaint's only concrete allegation about relative cost. (*See* Compl. ¶ 156 (alleging that Abbott touted Depakote as a "lower cost" alternative to the "much more costly" Lamictal).)

Abbott's asking price as a result of those statements, and Depakote performed as advertised, there is no "injury," as Plaintiffs got exactly what they expected when they agreed to Abbott's asking price. That Plaintiffs might have found a *better* bargain is irrelevant to whether they received the benefit of the bargain they made. *See Ironworkers*, 634 F.3d at 1360, 1363 ("that the payer merely paid for more expensive drugs does not suffice"); *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *69 ("allegations that there are more 'cost-effective' alternatives do not [state] a concrete financial loss").

4. Plaintiffs' Alleged Injury Is Illusory Because They Would Be In The Same Position Absent The Alleged RICO Violations

Finally, even if Plaintiffs did pay for one or more Depakote prescriptions that were "ineffective," their injury is illusory, because they would be in the same financial position if the alleged RICO violations had never occurred.

As the Eleventh Circuit explained in a similar off-label RICO case, TPPs do not pay for their beneficiaries' prescriptions out of charity. *Ironworkers*, 634 F.3d at 1368. Rather, they "charge their enrollees an up-front fee, i.e., a 'premium,' in exchange for [prescription-drug] coverage." *Id.* at 1364. Using sophisticated actuarial methods, TPPs set their premiums at a level such that the total premium payments collected will cover the cost of all beneficiaries' prescriptions—"including medically unnecessary or inappropriate prescriptions"—plus the TPPs' overhead expenses. *Id.* at 1364-65, 1368. In other words, the higher the overall cost of beneficiaries' prescriptions, the higher the premiums. Any "losses" due to payment for "unnecessary" prescriptions are therefore borne by the beneficiaries through increased premium payments, not by the TPP. *See id.* at 1369 (dismissing TPPs' claims for lack of a "plausibl[e]… economic injury"); *Health Care Serv. Corp. v. Olivares*, 2011 U.S. Dist. LEXIS 117750, at *18 (E.D. Tex. Sept. 2, 2011) (following *Ironworkers*).

The Seventh Circuit employed the same reasoning in affirming the dismissal of a TPP RICO case involving fraudulent cigarette marketing:

> Plaintiffs say that they are injured by the amount they pay to provide medical care for smokers….[However,] it is necessary to consider both the income and the expenditure sides of the insurer's balance sheet. The income side…includes higher premiums paid by smokers….Having collected extra money *from the smokers*…to cover the eventual illness, an insurer can't turn around and collect from the tobacco manufacturer for the same outlay….
>
> Our point is that smokers…pay for the medical costs, in advance, through higher insurance rates….[TPPs] are just financial intermediaries. They collect the premiums and spend them to provide the contracted-for care; their books balance whether the costs of care are high or low….[P]urchasers of insurance, not the [TPPs], foot the medical bill in the end.

Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc., 196 F.3d 818, 823-24 (7th Cir. 1999).

These cases' holdings comport with the fundamental principle that "damages…under RICO" are intended to "place [plaintiffs] in the same position they would have been in but for the illegal conduct." *Comm. Union Assurance Co. PLC v. Milken*, 17 F.3d 608, 612 (2d Cir. 1994). Where the alleged illegal conduct *created* the very property interest alleged to have been lost, "restoring" it to the plaintiff would leave her in a *better* position than she would have been in absent that illegal conduct. *See McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 228 (2d Cir. 2008) (no RICO claim where the "property to which a plaintiff alleges injury…would not have existed but for the alleged RICO violation"), *abrogated in part on other grounds by Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008).

Here, but for Abbott's alleged "scheme to increase sales of…Depakote" (Compl. ¶ 1), prescription rates for Depakote would have remained at their "correct" level. Plaintiffs' actuaries would have used *those* prescription rates—not the "inflated" prescription rates—in calculating

their expected annual outlay for Depakote, and Plaintiffs would have set their premiums based on *those* figures. Plaintiffs would have collected *those* premiums, not the higher premiums they collected in the real world. It is true that, in this alternate reality, Plaintiffs would have paid Abbott less for Depakote—but because Plaintiffs' premiums would have been based on the "correct" prescription rates, they would end up exactly where they are now: "their books balance whether the costs of [Depakote] are high or low." *Philip Morris*, 196 F.3d at 824.[13]

Under these circumstances, awarding Plaintiffs the "hundreds of millions of dollars they paid to…Abbott…as a result of [its] scheme to increase sales" (Compl. ¶ 1) would not place Plaintiffs "in the same position they would have been in but for the illegal conduct." *Milken*, 17 F.3d at 612. Instead, it would give them an enormous windfall.

B. Plaintiffs Fail To Plead Causation

Only someone injured "by reason of" a RICO violation may sue. 18 U.S.C. § 1964(c). This language imposes both a "but-for" and a proximate causation requirement. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992). Plaintiffs plead neither.

1. "But-For" Causation

To satisfy RICO's "but-for" causation requirement, the plaintiff must show that, absent the defendant's racketeering activity, the claimed injury would not have occurred.[14] Here, "[w]hile Plaintiffs have gone to great lengths to chronicle [Abbott's] alleged conduct, they fail to

[13] While the Complaint does not describe the process by which Plaintiffs set their premiums, a court must "draw on…common sense" even at the 12(b)(6) stage. *Iqbal*, 556 U.S. at 679. Because Plaintiffs "pled no facts…that suggest [they] established premiums in a way inconsistent with the insurance industry's conventional ratemaking procedures," the Court "must…infer" that they employed those procedures—and, thus, "that they adjusted their premiums upward to reflect the projected value of claims for [the off-label] prescriptions" at issue. *Ironworkers*, 634 F.3d at 1368; *accord Olivares*, 2011 U.S. Dist. LEXIS 117750, at *18 (assuming, on motion to dismiss, that TPP "set its premiums in…the conventional manner outlined…in *Ironworkers*" where "there [was] nothing in the complaint to suggest" otherwise).

[14] Notably, the injury must stem not just from the defendant's conduct *in general*, but from the defendant's specified indictable *acts of racketeering*. *Beck v. Prupis*, 529 U.S. 494, 495-96 (2000).

allege the connection between" the predicate acts of racketeering "and Plaintiffs' injuries." *Janssen*, 784 F. Supp. 2d at 523-24. Dismissal is therefore required.

The Complaint contains nothing more than boilerplate allegations that Abbott's conduct "cause[d] Plaintiffs…to pay for [off-label] Depakote prescriptions," and that "[a]bsent Abbott's improper conduct," this would not have occurred. (Compl. ¶ 204.) But a "formulaic recitation of [an] element[] of a cause of action will not do." *Iqbal*, 556 U.S. at 678; *see Actimmune*, 614 F. Supp. 2d at 1051 ("mere recitations of the causation element of [a] RICO claim" insufficient).

The Complaint does not plead that a single one of Plaintiffs' beneficiaries' physicians saw an off-label promotional statement by Abbott, let alone relied on it in writing a Depakote prescription for which Plaintiffs paid. As discussed above, off-label *prescription* is a "ubiquit[ous]" practice, even absent unlawful off-label *promotion*. *King-Vassel*, 2013 U.S. App. LEXIS 17989, at *4. Without concrete allegations establishing a causal link between Abbott's promotion and Plaintiffs' payments, the Complaint at most "pleads facts that are 'merely consistent with'" liability. *Iqbal*, 556 U.S. at 678. Courts have dismissed numerous TPP off-label RICO actions for just this reason. *See Actimmune*, 614 F. Supp. 2d at 1052-53 ("Plaintiffs need to allege what specific information…their physicians had...[and] the extent to which they relied upon that information….The court will not make the unsupported inference that…plaintiffs purchased the drug as a result of defendants' [promotion]."); *accord In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 111446, at *220-23 (N.D. Cal. Aug. 2, 2012); *S. Ill. Laborers & Emp'rs Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414, at *19-20 (S.D.N.Y. Sept. 30, 2009); *Janssen*, 784 F. Supp. 2d at 523-24; *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *90; *Olivares*, 2011 U.S. Dist. LEXIS 117750, at *24-25.

2. Proximate Causation

RICO's proximate-cause requirement "demand[s]" a "*direct* relation between the injury asserted and the injurious conduct alleged." *Holmes*, 503 U.S. at 268-69 (emphasis added); *see also Anza v. Ideal Supply Corp.*, 547 U.S. 451, 457-61 (2006) ("the central question…is whether the alleged violation led directly to the plaintiff's injuries"). In other words, RICO liability does "not…go beyond the first step" in the causal chain. *Holmes*, 503 U.S at 271; *see also Hemi Grp. v. City of New York*, 559 U.S. 1, 9-10 (2010) (plurality) (plaintiff's "theory of causation" may not involve more than one "step"); *Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994) (finding lack of proximate cause where causal chain "pass[ed] through many intermediaries" and plaintiff's damages "require[d] actions and decisions by third parties before coming into being"). This requirement serves important purposes, for "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the [RICO] violation, as distinct from other, independent factors." *Holmes*, 503 U.S. at 269.

Injuries suffered by TPPs are "indirect" by definition. As a textbook example of indirect injury, the Supreme Court has stated the following: "A, who had agreed with a town to support all the town paupers for a specific period, in return for a fixed sum, ha[s] no cause of action against S for assaulting and beating one of the paupers, thereby putting A to increased expense." *Assoc. Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 533 n.25 (1983) (cited with approval by *Holmes*, 503 U.S. at 267-70).

In a TPP action based on off-label promotion, the causal chain is even more indirect. In one such case, the Second Circuit described the "attenuated link between the alleged misrepresentations…and the ultimate injury" as follows:

> [(1)] Lilly distributes misinformation about Zyprexa, [(2)] physicians rely upon the misinformation and prescribe Zyprexa, [(3)] TPPs relying on the advice of [outside pharmacy benefit

> managers] and their Pharmacy and Therapeutics Committees place Zyprexa on their formularies as approved drugs, [(4)] TPPs fail to negotiate the price of Zyprexa below the level set by Lilly, and [(5)] TPPs overpay for Zyprexa.

UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 134 (2d Cir. 2010).

For this reason, courts have almost uniformly "concluded that the injury for which third party payors seek reimbursement" in off-label promotion cases "is too remote and speculative to maintain a RICO claim." *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *20; *see, e.g.*, *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 (11th Cir. 2011) ("[I]t cannot reasonably be inferred that Bayer's…conduct led directly to Southeast's decision to pay for Trasylol."); *UFCW Cent. Pa. v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (plaintiff's "causal theory is too attenuated to satisfy the…proximate causation requirement"); *Emp'r Teamsters-Local Nos. 17/505 Health Welfare Trust Fund v. Bristol Myers Squibb Co.*, 2013 U.S. Dist. LEXIS 21589, at *32 (S.D. W. Va. Jan. 29, 2013) ("Between Defendants' [off-label] marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events."). Notably, the Seventh Circuit has held that this same principle bars TPPs' RICO claims against cigarette manufacturers. *See Philip Morris*, 196 F.3d at 825 ("The injury for which plaintiffs seek compensation is remote indeed, the chain of causation long….").

Moreover, "[t]he role of the prescribing physician" in the causal chain is especially "problematic." *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *24 n.9. As learned professionals, doctors "are presumed to go beyond advertising…and use their independent knowledge in making medical decisions." *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1280-82 (S.D. Fla. 2009), *aff'd*, 444 F. App'x 401 (11th Cir. 2011). "There are numerous factors that could influence a physician when deciding to prescribe a certain drug," *Janssen*, 784 F. Supp. 2d at 523-24, "only one of which might be the drug manufacturer's

promotions and literature," *Ironworkers*, 634 F.3d at 1362; *see also Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *25-26 (listing various factors considered by doctors other than advertising).

Thus, "establishing that Plaintiffs' injuries were caused by [Abbott's] misconduct would require an inquiry into the specifics of each doctor-patient relationship…with regard to each… reimbursement payment." *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008), *aff'd*, 634 F.3d 1352 (11th Cir. 2011); *see also Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *25-26; *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *88-93. "Attempting to ascertain damages in this scenario[] would result in the type of speculative… analysis the direct proximate cause requirement is intended to prevent." *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *26 (quoting *Anza*); *cf. Anza*, 547 U.S. at 459 ("Businesses lose and gain customers for many reasons, and it would require a complex assessment to establish what portion of Ideal's lost sales were the product of [the alleged fraud].").

Plaintiffs will no doubt ask the Court to ignore the indirectness of their putative injuries because they were allegedly foreseeable, or were the result Abbott intended. But "[t]his argument…directly contradicts the relevant Supreme Court precedent." *Bextra*, 2012 U.S. Dist. LEXIS 111446, at *225; *see also SEIU Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1074 (D.C. Cir. 2001) (courts "have rejected the contention that specific intent…or…the foreseeable nature of the harms…is sufficient to satisfy the proximate cause requirement").

In *Anza*, the Second Circuit had found the proximate-cause requirement satisfied because the plaintiff was the "intended victim of the [defendant's] scheme." *Ideal Steel Supply Corp. v. Anza*, 373 F.3d 251, 257-64 (2d Cir. 2004), *rev'd*, 547 U.S. 451 (2006). The Supreme Court reversed, criticizing the lower court's reasoning "that because the Anzas allegedly sought to [harm] Ideal, it is immaterial whether they took an indirect route to accomplish their goal."

Anza, 547 U.S. at 460. The Court concluded that "[a] RICO plaintiff cannot circumvent" the directness requirement merely because the alleged injury was "the defendant's aim." *Id*. at 460; *see also James Cape & Sons Co. v. PCC Constr. Co.*, 453 F.3d 396, 403-04 (7th Cir. 2006).

Subsequently, in *Hemi*, the plurality noted *Anza*'s disavowal of "foreseeability" and "intent" in the proximate-cause analysis:

> The dissent would have RICO's proximate cause requirement turn on foreseeability, rather than on the existence of a sufficiently "direct relationship" between the fraud and the harm….[This] is precisely the argument lodged against the majority opinion in *Anza*. There, the dissent criticized the majority's view for "permit[ting] a defendant to evade liability for harms that are not only foreseeable, but the intended consequences of the defendant's unlawful behavior." But the dissent there did not carry the day…. Our precedents make clear that…the focus is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability.

559 U.S. at 12.

This Court should follow *Holmes*, *Anza*, and *Hemi*, and refuse to "stray from the direct relationship test by considering issues of foreseeability and intent." *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *26-27; *accord Bextra*, 2012 U.S. Dist. LEXIS 111446, at *225; *Se. Laborers*, 655 F. Supp. 2d at 1283; *Janssen*, 784 F. Supp. 2d at 525.

C. Plaintiffs Fail To Plead That Abbott Conducted An "Enterprise's" Affairs

RICO prohibits "any *person*…associated with any *enterprise*…to conduct…*such enterprise's* affairs" though a "pattern of racketeering activity." *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 160 (2001) (quoting 18 U.S.C. § 1962(c)) (emphasis added). Thus, "liability depends on showing" that the defendant (the RICO "person") conducted "the '*enterprise's* affairs,' not just [his] *own* affairs," through racketeering activity. *Richmond v. Nationwide Cassel L.P.*, 52 F.3d 640, 646 (7th Cir. 1995) (emphasis in original).

Here, even assuming the so-called CENE Enterprise, PharmaCare Enterprise, and

ABcomm Enterprise are viable RICO "enterprises," Plaintiffs' claim fails because the only "affairs" that Abbott allegedly "conduct[ed]" through racketeering activity were Abbott's own. *Cf. UFCW Unions & Emp'rs Midw. Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 854-55 (7th Cir. 2013) (affirming dismissal where "nothing in the complaint reveal[ed]" that defendants' acts of racketeering "were undertaken on behalf of the *enterprise* as opposed to on behalf of [defendants] in their individual capacities, to advance their individual self-interests").

This is most obviously true of the PharmaCare Enterprise, which consists of Abbott; Abbott's own sales representatives; and PharmaCare, a vendor Abbott hired to train its sales representatives. It is often said that "an employer and its employees cannot constitute a RICO enterprise," because the affairs of such an "enterprise" are just the affairs of the company. *Fitzgerald v. Chrysler Corp.*, 116 F.3d 225, 226 (7th Cir. 1997); *see also Stachon v. United Consumers Club, Inc.*, 229 F.3d 673, 676 n.3 (7th Cir. 2000). But the same holds for an "enterprise" consisting of an employer, its employees, and a company brought in to train the employees to do the employer's bidding. The interest advanced when the employees subsequently perform the acts they were trained to perform is that of the employer.

A similar problem exists with the other two alleged "enterprises," which consist of Abbott, together with marketers and physicians Abbott allegedly paid to create and propagate its promotional messages. The Complaint does not plausibly establish that, in paying CENE, ABcomm, and their constituent physicians to promote Depakote, Abbott intended to advance the interests of the so-called CENE and ABcomm Enterprises, as opposed to Abbott's "individual self-interest[]." *Walgreen*, 719 F.3d at 854-55. Indeed, the Seventh Circuit has approvingly cited a case dismissing a RICO claim on this ground where "[t]he RICO person" was a corporation (Mobil), "and the enterprise was the [combination] of Mobil…and [the] advertising

and marketing agencies" that assisted Mobil in fraudulently promoting its products. *Richmond*, 52 F.3d at 647 (following *Brittingham v. Mobil Corp.*, 943 F.2d 297 (3d Cir. 1991)).

In sum, despite Plaintiffs' use of the magic word "enterprise," "[t]he nub of the complaint is that [Abbott] operate[d] *itself* unlawfully," and that is not enough. *Walgreen*, 719 F.3d at 855.

D. The Alleged Predicate Acts Of Racketeering Are Insufficiently Pled

A civil RICO plaintiff must plead "at least two predicate acts" found in 18 U.S.C. 1961(1)(B). *Midw. Grinding*, 976 F.2d at 1019. Here, Plaintiffs rely on alleged violations of the federal mail- and wire-fraud statutes (18 U.S.C. §§ 1341, 1343), the Travel Act (18 U.S.C. § 1952), and unspecified "state bribery statutes." (Compl. ¶¶ 229(n), 230, 234.) But the Complaint fails to adequate plead a violation of any of these statutes.

1. Mail And Wire Fraud

To plead mail or wire fraud, "a plaintiff must show a 'scheme or artifice to defraud'…." *Reynolds v. E. Dyer Dev. Co.*, 882 F.2d 1249, 1251 (7th Cir. 1989). This requires pleading that the defendant "lied," or engaged in conduct "calculated to deceive." *Id.* at 1251-53; *see also McEvoy Travel Bureau, Inc. v. Heritage Travel, Inc.*, 904 F.2d 786, 791 (1st Cir. 1990) ("[N]ot every use of the mails or wires in furtherance of an unlawful scheme to deprive another of property constitutes mail or wire fraud….Rather, the scheme must be intended to *deceive*….").

Here, Plaintiffs do not allege a single false or deceptive statement attributable to Abbott—let alone with the specificity required by Rule 9(b). *See Slaney*, 244 F.3d at 597 (Rule 9(b) requires plaintiff to "state the…content of the alleged false representations"). The Complaint is replete with general allegations that Abbott promoted Depakote off-label. However, as described above, there is no connection between off-label status and ineffectiveness. Thus, while it may violate the FDCA, "the promotion of off-label drug use is not in itself false or misleading." *Caronia*, 703 F.3d at 165; *see also Cent. Reg'l Emps. Benefit*

Fund v. Cephalon, Inc., 2009 U.S. Dist. LEXIS 93636, at *10-11 (D.N.J. Oct. 7, 2009); *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *37; *Actimmune*, 614 F. Supp. 2d. at 1051 n.6. Accordingly, Plaintiffs have not pled mail or wire fraud. *See Epogen*, 590 F. Supp. 2d at 1289-90 (distinguishing between actual "deceptive advertising" of a drug, which can constitute a predicate act of fraud, and mere "off-label promotion," which cannot).[15]

Moreover, Rule 9(b) "requires a [RICO] plaintiff to identify the time and place of the alleged predicate acts" of fraud. *Midw. Grinding*, 976 F.2d at 1020. Here, the RICO count of the Complaint (¶¶ 223-42) is devoid of any dates or locations. Scattered dates appear throughout the Complaint's 56-page facts section, but it is unclear which dates correspond to the predicate acts of mail and wire fraud alleged to have caused Plaintiffs' injury. It is "[im]proper" to "attempt to satisfy…[Rule] 9(b) through an incorporation of [an] entire complaint into the RICO claim," and doing so is "grounds enough" for dismissal. *Slaney*, 244 F.3d at 599 n.10.

2. State-Law Bribery And Travel Act Violations

The allegations of state-law bribery and Travel Act violations are also inadequate.[16] Although these are "not by definition fraudulent torts," Rule 9(b) nonetheless applies to these claims, as they are premised on the same "course of fraudulent conduct" as Plaintiffs' mail- and wire-fraud claims. *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507-08 (7th Cir. 2007). Moreover, a RICO complaint is always insufficient "if it does not specify the nature of

[15] It is no answer that Abbott allegedly failed to disclose its sponsorship of certain programs and materials that were not otherwise deceptive. A plaintiff cannot state a claim for mail or wire fraud based on "mere failure to disclose." *Reynolds*, 882 F.2d at 1252-53; *see, e.g., Ironworkers*, 634 F.3d at 1368 n.33 ("For…a theory based on [nondisclosure] to prove tenable, the insurers would need to establish that AstraZeneca owed them a legal duty of disclosure. No such duty exists, however, absent a special relationship between the parties."); *Epogen*, 2009 U.S. Dist. LEXIS 58697, at *18-19, *23 (Amgen's failure to "disclose that it sponsored many of the clinical studies which reported positive findings on unapproved uses of EPO" was "not actionable as fraud" because it lacked "a duty to disclose").

[16] The Travel Act prohibits use of interstate "facilit[ies]" to commit specified "unlawful activit[ies]." 18 U.S.C. § 1952(b). The only listed activity that appears remotely relevant is state-law bribery. *See id.* § 1952(b)(2). Plaintiffs' Travel Act allegations are thus duplicative of their bribery allegations.

the predicate acts to a degree that will allow the defendant to comprehend the specific acts to which [it is] required to answer." *Ray v. Karris*, 780 F.2d 636, 645 (7th Cir. 1985); *see also Jennings v. Emry*, 910 F.2d 1434, 1438 (7th Cir. 1990) ("[I]n pleading predicate acts conclusory allegations that various statutory provisions have been breached are of no consequence….").

Plaintiffs' boilerplate statements that Abbott violated the Travel Act and unspecified state-law bribery statutes are insufficient under any standard. *Cf. Janssen*, 784 F. Supp. 2d at 529 (predicate acts of state-law bribery insufficiently pled where complaint did not "delineate the elements of bribery, cite any particular bribery statute that was violated," or "assert any instances where Defendants provided remuneration to a physician and thereby caused [her] to prescribe Risperdal when it was not in the patient's best interest").

E. Plaintiffs' RICO Claims Are Time-Barred

Civil RICO's statute of limitations is four years. *Rotella v. Wood*, 528 U.S. 549, 552 (2000). It begins to run "when [the] plaintiff knew or should have known of his injury." *Id.* at 553; *see also McCool v. Strata Oil Co.*, 972 F.2d 1452, 1464-65 (7th Cir. 1992). The "should have known" prong is met when a "diligent" plaintiff would have discovered the fact of injury. *Cancer Found., Inc. v. Cerberus Capital Mgmt., LP*, 559 F.3d 671, 674 (7th Cir. 2009); *see also Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 187 (1997) (RICO requires "potential private plaintiffs diligently to investigate"). A plaintiff "does not need to know his injury *is actionable* to trigger the statute of limitations—the focus is on the discovery of *the harm itself*." *Cancer Found.*, 559 F.3d at 674-75 (emphasis added). Thus, the plaintiff's awareness of "the other elements of [a RICO] claim" is irrelevant. *Rotella*, 528 U.S. at 555. In a RICO case, "the question of inquiry notice need not be left to [the] finder of fact," and may be determined as a matter of law where appropriate. *Lanza v. Merrill Lynch & Co.*, 154 F.3d 56, 60 (2d Cir. 1998).

1. Plaintiffs' Claims Are *Prima Facie* Untimely

Plaintiffs' alleged injury is their loss of money spent on off-label Depakote prescriptions. These payments were made beginning in 1998. (Compl. ¶¶ 8, 12-14.) Plaintiffs' RICO claims accrued—and the limitations clock began to run—when they first made payment. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 195-96 (E.D.N.Y. 2008) (Weinstein, J.) (in off-label RICO case, TPPs' claims "accru[ed]…when payment for Zyprexa [was] made"), *rev'd on other grounds*, 620 F.3d 121 (2d Cir. 2010).

The *Zyprexa* court's finding on accrual is only logical. Those "who manage welfare benefit plans for employees and beneficiaries" are obligated to "act with the highest fiduciary duty known to the law"—and thus, must "remain…ever vigilant of their [beneficiaries'] interests." *Haviland v. Metro Life Ins. Co.*, 2013 U.S. App. LEXIS 18896, at *30-31 (6th Cir. Sept. 12, 2013); *see* 29 U.S.C. § 1104(a)(1). Accordingly, TPPs have a "continuing duty" to their beneficiaries "to inquire and to be aware of the value of drugs for which they [are] paying." *Zyprexa*, 253 F.R.D. at 76, 196. Moreover, as Judge Weinstein noted in *Zyprexa*, TPPs are "sophisticated institutions" with considerable "expertise in merchandising of [p]harmaceuticals." *Id*. at 195-96. As such, they know—perhaps better than anyone—that off-label use "is widespread." *Buckman*, 531 U.S. at 351 n.5. Finally, there is no question that TPPs have the ability "to monitor the prescription, dispensing, and use patterns of medications" to detect allegedly inappropriate off-label use. *Ironworkers*, 634 F.3d at 1366-67 & n.31.

Thus, Plaintiffs had the duty, motive, and ability to police for allegedly inappropriate off-label prescriptions throughout the class period. Had Plaintiffs exercised minimal diligence, to say nothing of the "highest fiduciary duty known to the law," they would have learned well more than four years ago that their beneficiaries were receiving allegedly improper off-label Depakote prescriptions, and that Plaintiffs were ostensibly being injured by paying for them. Accordingly,

Plaintiffs' RICO claims are untimely. *See Zyprexa*, 253 F.R.D. at 195 (court cannot "allow [TPPs'] passivity…to visit upon [manufacturer] enormous potential exposure, which could have been substantially limited had [they] exercised their responsibilities appropriately").

2. The "Separate Accrual" Rule Does Not Apply

In *Zyprexa*, the court concluded that the plaintiffs might still recover for payments they made during the four years immediately prior to filing suit, even though their RICO claims as to earlier payments were time-barred. 253 F.R.D. at 195. This claim-splitting approach is appropriate under some circumstances, and it might have been appropriate on the facts of *Zyprexa*—but it is not proper here.

Under the so-called "separate accrual" doctrine, a RICO plaintiff may recover for any "additional damages" it suffered due to "separable, new predicate act[s]" of racketeering committed within the four-year window preceding the filing of its complaint, even if it knew or should have known of its *original* injury more than four years before it filed suit. *Klehr*, 521 U.S. at 190. Of course, this principle cannot be used as a "bootstrap to recover for injuries caused by…predicate acts that took place" outside this four-year window. *Id.*; *see also McCool*, 972 F.2d at 1465-66 & n.10 ("a [separate] cause of action accrues only when there is a new instance of wrongful conduct *and* a new injury" (emphasis added)).

Here, the Complaint contains no particularized allegations of misconduct in the four years prior to the filing of this lawsuit (*i.e.*, after August 16, 2009)—let alone an adequately pleaded "predicate act" of racketeering that caused a distinct, new injury to Plaintiffs. *See Zalesiak v. UnumProvident Corp.*, 2007 U.S. Dist. LEXIS 92233, at *16-17 (N.D. Ill. Dec. 12, 2007) (doctrine did not apply where plaintiff "d[id] not allege new acts or new injuries" in the last four years "in her…Complaint"). Still less do Plaintiffs allege a new predicate act that is truly separable, and not merely a continuation of "the same…scheme" that they allege began

more than four years before suit was commenced. *Grimmett v. Brown*, 75 F.3d 506, 513-14 (9th Cir. 1996); *see Lanza*, 154 F.3d at 59-60 (collection of annual fees during the four years prior to filing suit was not "a separate and distinct fraud" from solicitation of initial investment). Thus, the "separate accrual" rule cannot salvage any portion of Plaintiffs' RICO claims.

3. Neither Equitable Estoppel Nor Equitable Tolling Applies

Plaintiffs allege that the limitations period should be extended because Abbott "conceal[ed]…its…off-label promotion," such that "Plaintiffs…could not reasonably have discovered" the alleged fraud in a timely fashion. (Compl. ¶¶ 199-202.) Plaintiffs thereby appear to invoke the doctrines of equitable estoppel and/or equitable tolling.

Equitable estoppel—sometimes also known as fraudulent concealment—"comes into play when a defendant takes active steps to prevent a plaintiff from suing on time," such as "promising not to plead the statute of limitations," or "present[ing] [the plaintiff] with forged documents purporting to negate any basis" for her suit. *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 450-51 (7th Cir. 1990). It does not apply merely because the defendant "committed [acts] during the course of the original fraud that ha[d] the effect of concealing the fraud from its victims." *Wolin v. Smith Barney Inc.*, 83 F.3d 847, 851-52 (7th Cir. 1996); *see also Cada*, 920 F.2d at 451. "The plaintiff must plead with particularity the circumstances surrounding the fraudulent concealment." *Grimmett*, 75 F.3d at 514; *see also Hentosh v. Herman M. Finch Univ. of Health Sci.*, 167 F.3d 1170, 1174-75 (7th Cir. 1999) (complaint must contain "allegation[s] supporting the application of the doctrine"); *Zalesiak*, 2007 U.S. Dist. LEXIS 92233, at *18.

Here, equitable estoppel is unavailable because Plaintiffs do not allege—let alone with particularity—that Abbott took "active steps" to prevent them from timely filing suit. That Abbott allegedly committed its underlying misconduct in a clandestine fashion is not enough, *Wolin*, 83 F.3d at 851-52; *Cada*, 920 F.2d at 451, and Plaintiffs' recitation of the stock phrase

"active concealment" is insufficient even under ordinary notice-pleading standards.

Equitable tolling, by contrast, applies where "the plaintiff, despite all due diligence, is unable to obtain vital information bearing on the existence of his claim." *Chakonas v. City of Chicago*, 42 F.3d 1132, 1135 (7th Cir. 1994). Typically, this occurs where the plaintiff "know[s] that he has been injured," such that the limitations clock has started to run, "but he cannot obtain information necessary to decide whether the injury is due to wrongdoing and, if so, wrongdoing by the defendant." *Cada*, 920 F.2d at 451. To invoke the doctrine, a complaint must allege facts "showing that a reasonable person exercising due diligence would not have been aware of the *possibility* of a claim," and that the plaintiff "exercised due diligence in order to obtain the [relevant] information." *Hentosh*, 167 F.3d at 1175 (emphasis added); *see also Zalesiak*, 2007 U.S. Dist. LEXIS 92233, at *19.

Importantly, "equitable tolling does not reset the statute of limitations," giving the plaintiff a full four years to sue from the time the necessary information comes to light. *Ashafa v. City of Chicago*, 146 F.3d 459, 464 (7th Cir. 1998). Rather, the doctrine provides a brief window in which to file, notwithstanding that the limitations clock has run. *Id.*; *see also Elmore v. Henderson*, 227 F.3d 1009, 1013 (7th Cir. 2000) (plaintiff "could not possibly invoke the doctrine…unless he sued just as soon as possible"). Even a delay of several months after the relevant information becomes available is too long. *See id.* (no tolling where plaintiff "waited four months to sue"); *Hentosh*, 167 F.3d at 1175 (same, almost seven months); *Cada*, 920 F.2d at 453 (same, eight months); *Thelen v. Marc's Big Boy Corp.*, 64 F.3d 264, 268 (7th Cir. 1995) (same, almost ten months). Thus, the doctrine of equitable tolling could only help Plaintiffs if, despite all due diligence, they could not have discovered even "the *possibility* of a claim" against Abbott until just before they filed suit in August 2013. *Hentosh*, 167 F.3d at 1175.

Here, the Complaint fails to plead concrete facts showing that this is the case. *See id.*; *Zalesiak*, 2007 U.S. Dist. LEXIS 92233, at *19. Indeed, the public record *forecloses* a finding of diligence. As discussed above, Abbott disclosed that federal authorities were investigating its marketing of Depakote in November 2009, a fact that was widely reported. A diligent TPP, aware that it had paid for many Depakote prescriptions, would have learned of "the *possibility* of a claim" at that time. Yet Plaintiffs did not file suit for almost four years after that date. Indeed, even after Abbott *pleaded guilty* in 2012, Plaintiffs waited another fifteen months to sue.

If delays of four, seven, eight, and ten months are enough to preclude equitable tolling, *see Elmore*, 227 F.3d at 1013; *Hentosh*, 167 F.3d at 1175; *Cada*, 920 F.2d at 453; *Thelen*, 64 F.3d at 268, then as a matter of law, Plaintiffs' years-long delay was excessive here. That Plaintiffs are sophisticated entities, and are represented by the same counsel as the lead *qui tam* plaintiff, only makes their delay even more inexcusable.

F. The First Circuit's *Neurontin* Decision Should Not Be Followed

Plaintiffs' opposition will no doubt rely heavily on *In re Neurontin Mktg. & Sales Practices Litig. (Kaiser)*, 712 F.3d 21 (1st Cir. 2013), *petition for cert. filed* (No. 13-289, Aug. 30, 2013). *Neurontin* is the sole appellate decision—if not the sole decision, period—permitting a TPP to recover against a pharmaceutical manufacturer under RICO for off-label promotion.

At the outset, even if this Court were to find *Neurontin* persuasive across the board, dismissal would still be required for several reasons:

- *Neurontin* does not hold that mere payment for an off-label prescription constitutes a RICO injury. Rather, the plaintiff, Kaiser, established that Neurontin was *actually ineffective* for specific off-label uses for which it had been prescribed to Kaiser's beneficiaries. *Id.* at 28, 32, 47.

- *Neurontin* declined to address the point—which, under *Philip Morris*, is the binding law of this circuit—that a TPP's injury in such a case is illusory. *Neurontin*, 712 F.3d at 47 n.18 (noting that "neither party…ha[d] raised" this argument).

- *Neurontin* did not address whether Pfizer's racketeering activity was intended to benefit a separate RICO "enterprise," rather than to advance its own self-interest.

- *Neurontin* (which was an appeal following a jury verdict) did not address whether Pfizer's predicate acts of racketeering were sufficiently pled in Kaiser's complaint.

- *Neurontin* did not involve a statute-of-limitations defense.

Furthermore, *Neurontin* is at odds with the many authorities cited above on "but-for" and proximate cause. On those two issues, *Neurontin*'s anomalous holding is flawed, and this Court should decline to follow it. *See generally* "On Litigation, Great and Small," *Drug and Device Law*, Sept. 19, 2013, http://druganddevicelaw.blogspot.com/2013/09/on-litigation-great-and-small.html (criticizing *Neurontin* and discussing overwhelming weight of contrary authority).

1. *Neurontin* And "But-For" Causation

Neurontin went astray in its "but-for" causation analysis by holding that Kaiser need not adduce proof that its beneficiaries' physicians actually relied on Pfizer's off-label marketing. Instead, the First Circuit permitted "but-for" causation to be established using "aggregate data"—*i.e.*, a "statistical" correlation between Pfizer's spending on off-label promotion and increases in Neurontin prescriptions. 712 F.3d at 29-30.[17]

This conclusion is contrary to the many RICO decisions cited above, which correctly required allegations (and, subsequently, evidence) that *specific prescriptions* resulted from *specific physicians'* reliance on *specific statements* by the manufacturer. *See, e.g.*, *Eli Lilly*, 620 F.3d at 134-35 ("generalized proof of reliance" does not suffice due to the numerous "considerations…taken into account" by each prescribing physician); *SEIU*, 249 F.3d at 1074 ("[r]eliance on aggregate statistical proof…does not alter the speculative nature of the claimed

[17] Kaiser at least adduced evidence that its beneficiaries' physicians *were actually exposed to* Pfizer's off-label marketing. 712 F.3d at 40-41. Here, by contrast, Plaintiffs make no such allegations.

damages"); *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *84-89 ("aggregate proof…is not a viable theory for demonstrating RICO causation"); *Janssen*, 2008 U.S. Dist. LEXIS 103526, at *23-24 n.8 ("statistical modeling" does not "satisfy [the] burden of pleading causation").

Moreover, this conclusion is contrary to the law of this circuit. In *Philip Morris*, the Seventh Circuit held that individual beneficiaries' "reli[ance]…on tobacco producers' statements" was "a central question…that cannot be dodged by the device of an insurer's direct suit." 196 F.3d at 823. As the Seventh Circuit noted, the *Neurontin* approach—allowing causation to be established *en masse* through statistical hand-waving—unfairly "strip[s]" manufacturers "of [the] defense[]" of lack of reliance. *Id.*; *cf. Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2561 (2011) ("a class cannot be certified on the premise that Wal-Mart will not be entitled to litigate its statutory defenses to individual claims").

2. *Neurontin* And Proximate Causation

The First Circuit held that Kaiser had satisfied RICO's proximate-cause requirement because its payment for ineffective Neurontin prescriptions "was plainly foreseeable," and because it was "the intended victim" of Pfizer's conduct. 712 F.3d at 38. The court erroneously regarded a stray remark from *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), as endorsing this "foreseeability" standard. Properly read, however, *Bridge* does no such thing.

In *Bridge*, the defendants prevented the plaintiffs from winning a series of auctions by submitting fraudulent bids. The question presented was whether a RICO plaintiff "must plead and prove that it" (as opposed to a third party) "relied on" the defendant's misrepresentations. *Id.* at 641-42. The Supreme Court noted that a RICO plaintiff must "show[] that *someone* relied" on the misrepresentations in order "to satisfy the element of causation." *Id.* at 658. However, for several reasons, it held that "first-party" reliance was not required.

In the relevant portion of its opinion, the Supreme Court rejected the argument that

Holmes and *Anza* implicitly require "first-party" reliance. The Court took as a given that "the central question" in the proximate-cause analysis is "whether the alleged violation *led directly* to the plaintiff's injuries," and that proximate cause is absent where "other, independent, factors" may have contributed to the plaintiff's damages. *Id.* at 654 (emphasis added). However, the Court concluded, "first-party" reliance is not always "necessary to ensure…a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy…*Holmes* and *Anza*." *Id.* at 657-58.

This is logical enough: even though the *Bridge* plaintiffs did not *rely* on the defendants' bids, those bids directly and immediately harmed them by causing them to lose the auctions. *See Hemi*, 559 U.S. at 14 ("[T]he…theory of causation in *Bridge* was 'straightforward'… each time a fraud-induced bid was awarded, [plaintiffs were] necessarily passed over."). The injury was not contingent on intervening events, and there were "no independent factors" (such as the judgment of learned professionals) that could have "account[ed] for" it. *Bridge*, 553 U.S. at 658.

In the midst of this discussion, the *Bridge* Court remarked that the plaintiffs' injury "was a foreseeable and natural consequence of [the defendants'] scheme." *Id.* But this comment was *dictum*. The Court cited no case law in connection with it. Nor did the Court remotely suggest that it was overruling—or even limiting—*Anza*, a case it cited with approval. As discussed above, *Anza* squarely rejected a "foreseeability" or "intent" standard of proximate cause; the First Circuit erred by elevating *Bridge*'s "foreseeable" *dictum* over *Anza*'s express holding.

In addition to incorrectly applying a "foreseeability" standard, the First Circuit erred in holding that the exercise of doctors' "independent medical judgment" was irrelevant to the proximate-cause inquiry. *Neurontin*, 712 F.3d at 39. In support of this conclusion, the First Circuit could not rely on *Bridge*, since that decision emphasized the *importance* of a lack of

"independent factors that [might] account for [the plaintiff's] injury." 553 U.S. at 658; *accord Holmes*, 503 U.S. at 269; *Anza*, 547 U.S. at 458; *Hemi*, 559 U.S. at 15. The First Circuit therefore relied—inexplicably—on Justice Thomas's *dissent* in *Anza*, which was joined by no other Justice, and whose reasoning the Court's majority rejected.

II. Plaintiffs Fail To State A RICO Conspiracy Claim

Plaintiffs assert not only a substantive RICO claim under 18 U.S.C. § 1962(c), but also a claim under § 1962(d) for "conspir[acy] to violate" RICO. However, "[s]ince [Plaintiffs] fail to establish a violation of section 1962(c), their section 1962(d) claim based on the same facts must fail as well." *Stachon*, 229 F.3d at 677; *see also Walgreen*, 719 F.3d at 856-57.

III. Plaintiffs Fail To State A Claim Under State Consumer-Protection Statutes

Plaintiffs also allege violations of the Illinois Consumer Fraud Act, 815 ILCS 505/2 ("ICFA"), and New York General Business Law § 349 ("§ 349"). Five of the RICO claims' shortcomings also doom these state-law claims. *Cf. Bextra*, 2012 U.S. Dist. LEXIS 111446, at *232-33 (dismissing ICFA claim alongside RICO claim); *S. Ill. Laborers*, 2009 U.S. Dist. LEXIS 91414, at *25 (same as to both ICFA and § 349 claims).

First, Plaintiffs' consumer-fraud claims are subject to Rule 9(b). *Pirelli*, 631 F.3d at 441, 446-47. As discussed above, the Complaint fails to articulate the time, place, and content of the fraudulent statements that allegedly injured Plaintiffs, and fails to plead "firsthand facts or data" showing that Plaintiffs were affected by the alleged fraudulent scheme. *Id*. at 445.

Second, both statutes require materially deceptive conduct. *Connick v. Suzuki Motor Co.*, 175 Ill. 2d 482, 504, 675 N.E.2d 584, 594 (1996); *Goshen v. Mut. Life Ins. Co.*, 774 N.E.2d 1190, 1195 (N.Y. 2002). As discussed above, while off-label promotion may be unlawful, it is not inherently *deceptive*. *See Anthony v. Country Life Mfg., L.L.C.*, 2002 U.S. Dist. LEXIS 19445, at *3-7 (N.D. Ill. Oct. 7, 2002) (FDCA violation did not establish ICFA violation), *aff'd*,

70 F. App'x 379 (7th Cir. 2003); *cf. Brissenden v. Time Warner Cable*, 885 N.Y.S.2d 879, 886 (N.Y. Sup. Ct. 2009) ("mere" violation of federal law "does not establish" § 349 claim).[18]

Third, both statutes require "actual damage." *Frye v. L'Oreal USA, Inc.*, 583 F. Supp. 2d 954, 957 (N.D. Ill. 2008); *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 897-98 (N.Y. 1999). As with RICO, the damage must be "concrete" and "ascertainable," rather than "[t]heoretical." *Frye*, 583 F. Supp. 2d at 957-58. For the reasons described above, Plaintiffs have failed to plead any cognizable damage. *See Baron v. Pfizer, Inc.*, 840 N.Y.S.2d 445, 448 (N.Y. App. Div. 2007) (in § 349 case, plaintiff's mere payment for off-label prescription was not "actual harm" absent allegation that drug "was ineffective to treat her neck pain"); *Verb v. Motorola*, 284 Ill. App. 3d 460, 472, 672 N.E.2d 1287, 1295 (1996) (in ICFA case, no harm where plaintiffs alleged they were injured by purchasing a product whose safety was "unproven").

Fourth, both statutes require a showing of causation. *Oliveira v. Amoco Oil Co.*, 201 Ill.2d 134, 148, 776 N.E.2d 151, 160 (2002); *Stutman v. Chem. Bank*, 731 N.E.2d 608, 611-12 (N.Y. 2000). As already discussed, Plaintiffs fall short here as well. *See DeBouse v. Bayer AG*, 235 Ill.2d 544, 560, 922 N.E.2d 309, 319 (2009) (no viable ICFA claim where plaintiff "fail[ed] to allege that her particular doctor was actually deceived by any of Bayer's advertisements"; allegation of "general deception of…the medical community" was insufficient).[19]

Fifth and finally, Plaintiffs' claims under both statutes are untimely.

Under the ICFA, the three-year statute of limitations accrues once the plaintiff "knew, or

[18] Moreover, to the extent Plaintiffs' state-law claims are premised "solely upon a violation of the FDCA," they are impliedly preempted, because the FDCA precludes private enforcement. *Anthony*, 2002 U.S. Dist. LEXIS 19445, at *8-9; *see also Epogen*, 590 F. Supp. 2d at 1290 (plaintiffs may not "shoehorn allegations that Defendants have…violat[ed]…the FDCA into…state consumer fraud causes of action").

[19] These statutes also impose a "directness" requirement akin to RICO's. *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris U.S.A., Inc.*, 818 N.E.2d 1140, 1145 (N.Y. 2004) ("a third-party payer [may not sue] under…§ 349 because its claims are too remote"); *Philip Morris*, 196 F.3d at 827-28 (Illinois "enforce[s] the normal rule that a third-party payor may recover as a subrogee or not at all").

reasonably should have known, that it was injured *and* that the cause of its injury was wrongful." *Indep. Trust Corp. v. Fid. Nat'l Title Ins. Co.*, 577 F. Supp. 2d 1023, 1041 (N.D. Ill. 2008) (emphasis added). Knowledge that an injury was "wrongfully caused" merely requires "notice…of a possible invasion of one's legally protected interests," and does not require specific knowledge of the of the defendant's conduct, or awareness that one has a valid cause of action. *Knox College v. Celotex Corp.*, 88 Ill.2d 407, 415, 430 N.E.2d 976, 980-81 (1981).

As discussed above, Plaintiffs should have known that they were injured (*i.e.*, that they had paid for off-label Depakote prescriptions) from the very beginning of the class period, and in all events, well more than three years before they filed suit on August 16, 2013. And, as a matter of law, Plaintiffs had "sufficient notice…of a possible invasion of [their] legally protected interests" more than three years before that date. Abbott disclosed the Department of Justice investigation in November 2009, and the court in *In re Subpoenas* detailed the nature of the investigation in March 2010. Both events were widely covered in the national media. This was enough to put a reasonable TPP on notice that it had at least potentially been wronged.

Under § 349, the statute of limitations is three years from the date "when plaintiff is injured by the deceptive act or practice," and "is not dependent upon [the] date when discovery of the alleged deceptive practice is said to occur," or the date of "discovery of…injury." *Statler v. Dell, Inc.*, 775 F. Supp. 2d 474, 484 (E.D.N.Y. 2011); *see also Wender v. Gilberg Agency*, 716 N.Y.S.2d 40, 41-42 (N.Y. App. Div. 2000) ("the date of discovery rule is not applicable"). Thus, Plaintiffs' § 349 claims are time-barred on their face.

IV. Plaintiffs Fail To State A Claim For Unjust Enrichment

Finally, Plaintiffs assert common-law unjust enrichment. "[I]f an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim…will stand or fall with the related claim." *Cleary v. Philip Morris, Inc.*, 656 F.3d 511,

517 (7th Cir. 2011); *see also Ass'n Benefit Servs. v. Caremark Rx, Inc.*, 493 F.3d 841, 855 (7th Cir. 2007). Because Plaintiffs' statutory claims fail, their unjust-enrichment claims fail as well.[20]

In any event, for the reasons already discussed, Plaintiffs have failed to plead that Abbott "has unjustly retained a benefit to [their] detriment," and that Abbott's "retention of the benefit violates the fundamental principles of justice, equity, and good conscience." *HPI Health Care Servs., Inc. v. Mt. Vernon Hosp. Inc.*, 131 Ill.2d 145, 160, 545 N.E.2d 672, 679 (1989); *accord Golden Pac. Bancorp v. F.D.I.C.*, 273 F.3d 509, 519 (2d Cir. 2001) (New York law); *Zotos v. Town of Hingham*, 2013 U.S. Dist. LEXIS 134123, at *55 (D. Mass. Sept. 19, 2013) (Massachusetts law). And, *a fortiori*, Plaintiffs have failed to plead this claim with the particularity required by Rule 9(b). *See Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 949 (7th Cir. 2013) (unjust enrichment must be pled with particularity when claim "emerge[s] out of a pattern of [allegedly] fraudulent conduct").

CONCLUSION

Plaintiffs apparently believe that they can cash in on Abbott's settlement with the government—despite the FDCA's lack of a private right of action—by doing little more than refiling the *McCoyd qui tam* complaint, substituting their own names in the caption, and reciting the elements of a RICO claim. For the reasons described above, this attempt must fail. Indeed, this case is a prime example of the "widespread abuse of civil RICO" the Seventh Circuit has decried. *Midw. Grinding*, 976 F.2d at 1025. The Complaint should be dismissed with prejudice.

[20] Thus, in off-label-promotion cases, courts routinely dismiss TPPs' unjust-enrichment claims in tandem with their RICO claims. *See, e.g., Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *32-33; *Ironworkers*, 585 F. Supp. 2d at 1346-47; *Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *120-21.

Respectfully submitted,
October 24, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on October 24, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following persons at the given e-mail addresses:

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